

# 11th Annual Meeting Angioplasty Summit 2006

## TCT Asia Pacific

Seoul, Korea – April 26 - 28, 2006



## “DES in the Treatment of SVG”



Dante  
Pazzanese

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# **DES in the Treatment of SVG**

**J. Eduardo Sousa, MD, PhD, FACC**

**No relationship to disclose.**

# Treatment of SVG Stenosis with DES

## Background

- Percutaneous revascularization of SVG lesions remains a challenge for interventional cardiologists.
- Balloon angioplasty in SVG lesions is associated with a complication rate and a high incidence of restenosis.
- Compared to balloon angioplasty, BMS implantation in SVG stenosis has been shown to improve procedural outcomes and reduce major cardiac events. However, the incidence of ISR remains 20% to 40%.

# **Real World Use of Sirolimus-Eluting Stents in Saphenous Vein Graft Disease: Data from the e-CYPHER Investigators.**

**J.Eduardo Sousa, Alexandre Abizaid, AH. Gershlick,  
G. Guagliumi, P. Guyon, C. Lotan, Ashok Seth, P.  
Urban, W. Wijns, J. Schofer, Jose R. Costa, G.  
Maldonado, Amanda Sousa  
On behalf of the e-CYPHER investigators**

# Background



- **The efficacy of sirolimus-eluting stents (SES) in the treatment of native vessel disease has been proven in several randomized trials.**
- **However, there is no data to support the use of SES for the treatment of saphenous vein graft (SVG) stenoses.**

# Goals and Design



- **Post-marketing surveillance registry to determine:**
  - **Safety and reliability of Sirolimus-eluting stents (SES) in routine clinical use**
  - **Reproducibility of RCT results**
  - **Use of SES world-wide in daily practice**
  - **Identification of MACE predictors**
- **All patients receiving  $\geq 1$  SES are enrolled**
- **Both on- and off-label use are recorded**
- **Clinical FU at one, six and twelve months**
- **No mandatory angiographic follow-up**
- **Recruitment completed WW = 15,556 patients**

# Structure

- Independent Advisory Board
- Independent Endpoint Committee  
(Chair M. Bertrand)
- Independent data management (Eminent - PPD)
- Independent data analysis (Hesperion Ltd)
- Audit check of ca. 3% of patients for data entry accuracy
- On-site data input via Internet

**281 sites  
41 countries**

**LATIN AMERICA 97**

Argentina 14  
Brazil 17  
Chile 8  
Colombia 9  
Costa Rica 2  
Dominican Republic  
2  
Guatemala 1  
Mexico 31  
Panama 3  
Uruguay 3  
Venezuela 7

**EUROPE 126**

Austria 7  
Belgium 4  
France 30  
Germany 1  
Italy 10  
Latvia 1  
Luxembourg 1  
Morocco 4  
Netherlands 1  
Portugal 9  
Russian Federation 4  
UK 4  
Spain 36  
Switzerland 9  
Lithuania 2  
Yugoslavia 1  
Tunisia 2

**MIDDLE EAST 15**

Bahrain 1  
Israel 11  
Lebanon 2  
Saudi Arabia 1

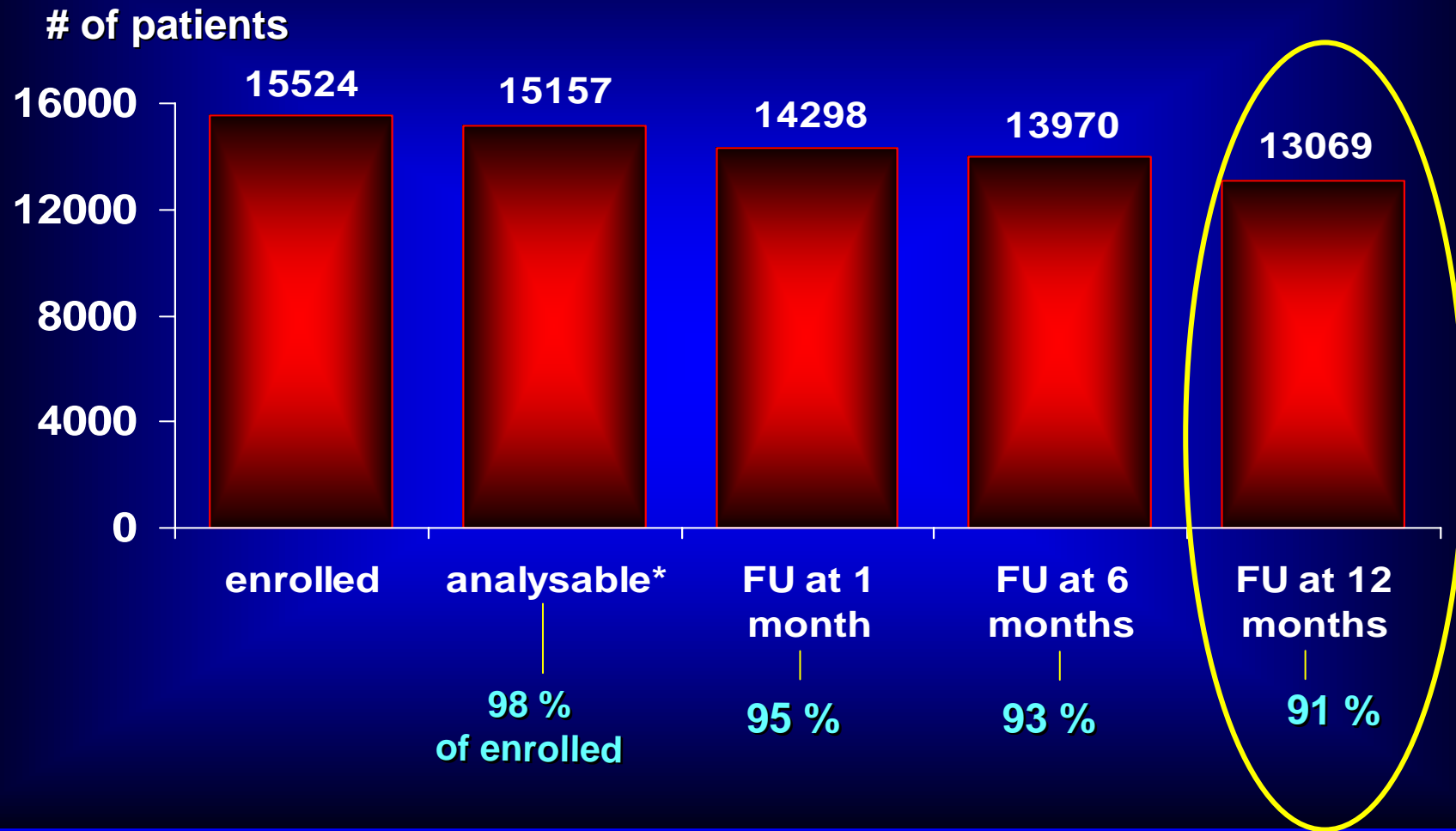
**ASIA PACIFIC 43**

Australia 11  
India 18  
Malaysia 3  
Pakistan 2  
Thailand 3  
Vietnam 2  
New Zealand 2  
Philippines 1  
Singapore

1



# Patient Enrolment



\* at least 1 SES in a CASS-defined coronary segment at a given index date

# Baseline Characteristics



	<b>SVG</b>	<b>Native</b>
<b>Number of patients</b>	<b>262 (2.0%)</b>	<b>14.910 (98%)</b>
<b>Age (years)</b>	<b>68.3 ± 9.57</b>	<b>61.6 ± 11.36</b>
<b>Male (%)</b>	<b>82.8</b>	<b>77.7</b>
<b>Current Smoker (%)</b>	<b>9.5</b>	<b>18.5</b>
<b>Hypertension (%)</b>	<b>69.5</b>	<b>62.0</b>
<b>Hyperlipidemia (%)</b>	<b>79.4</b>	<b>62.8</b>
<b>Diabetes (%)</b>	<b>34.0</b>	<b>28.4</b>
<b>Previous treatment with PTCA (%)</b>	<b>47.7</b>	<b>28.2</b>
<b>Previous treatment with CABG (%)</b>	<b>96.6</b>	<b>9.0</b>
<b>Multi-vessel disease (%)</b>	<b>86.7</b>	<b>56.3</b>
<b>Peripheral vascular disease (%)</b>	<b>7.3</b>	<b>12.6</b>

**p<0.001 for all variables**

# Angiographic Characteristics



	<b>SVG</b>	<b>Native</b>
Number of lesions	234	17965
● De novo (%)*	71.4	88.3
Type A / B1 (%)	13.7	14.3
Type B2 / C (%)	86.3	85.7
● Ref Vessel Diameter (mm)*	3.1 <sub>±</sub> 0.5	3.0 <sub>±</sub> 0.4
Lesion Length (mm)	17.8 <sub>±</sub> 10.9	17.2 <sub>±</sub> 8.8
● Thrombus (%)**	15	8.3
● Calcifications – moderate / heavy (%)***	14.5	21.3
TIMI 3 flow pre-procedure (%)	74.7	69.1
TIMI 3 flow post-procedure (%)	97.9	98

\* p<0.0001; \*\*p=0.0002; \*\*\*p<0.02      Patients treated at index with SVG and native lesion are not included

SVG

# PCI Procedure



	SVG	Native
● SES lesions / patient*	1.1±0.28	1.2±0.5
● SES / patient**	1.2±0.54	1.4±0.69
SES / lesion	1.1±0.39	1.1±0.36
● Multiple SES (%)***	16.8	26.3
Non-SES also implanted (%)	2.3	2.4
● Direct Stenting (%)*	47.9	33.8
Post dilation (%)	22.8	21.3
● Max deployment pressure (atm)*	15.8±3.1	14.2±2.8
Overlapping stents (%)	10.3	9.4

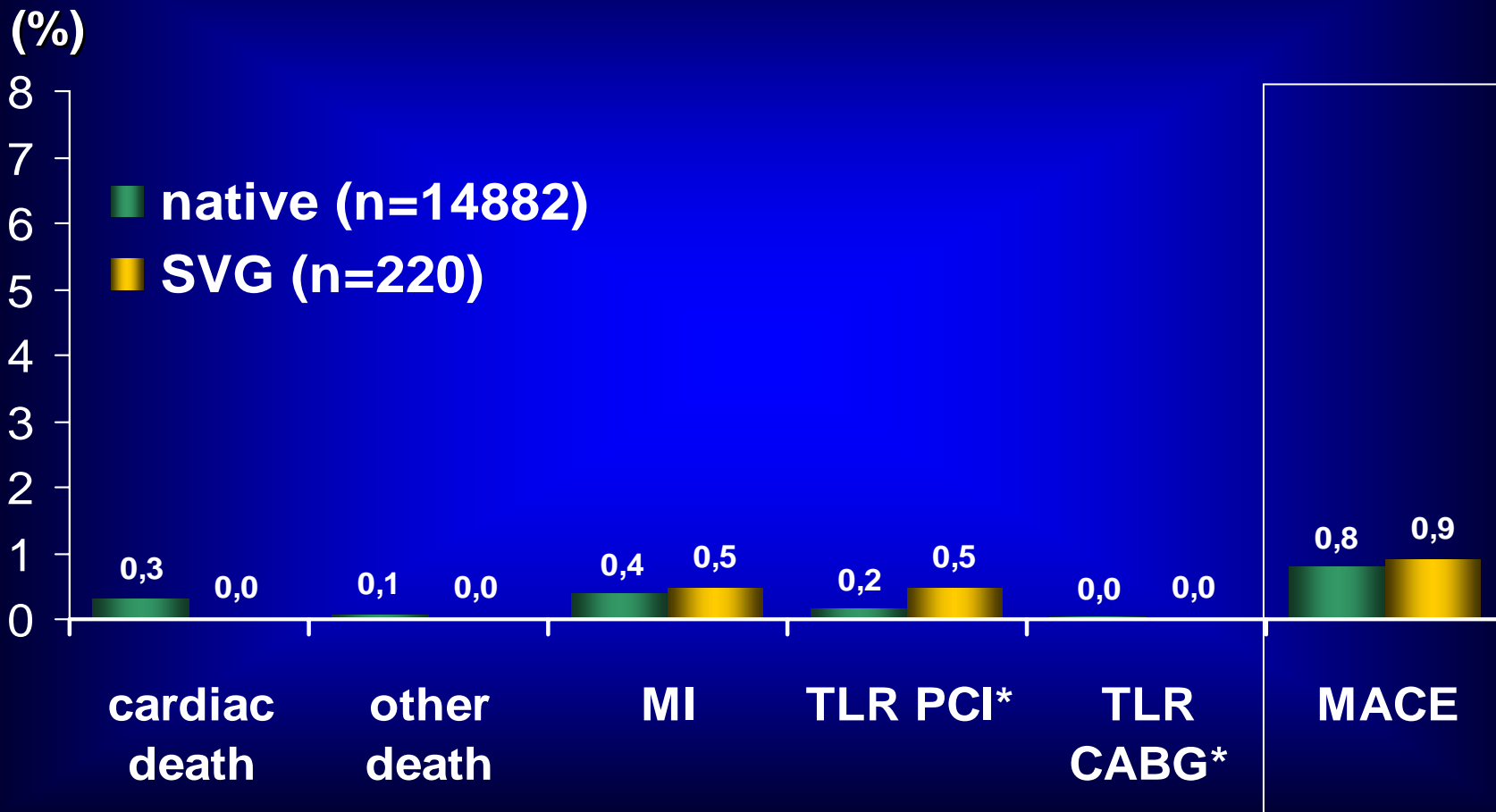
\* p<0.0001; \*\*p=0.0040 ; \*\*\*p=0.0015 Patients treated at index with SVG and native lesion are not included

SVG

# In-hospital MACE



## CEC-adjudicated events



\*Cypher stent related

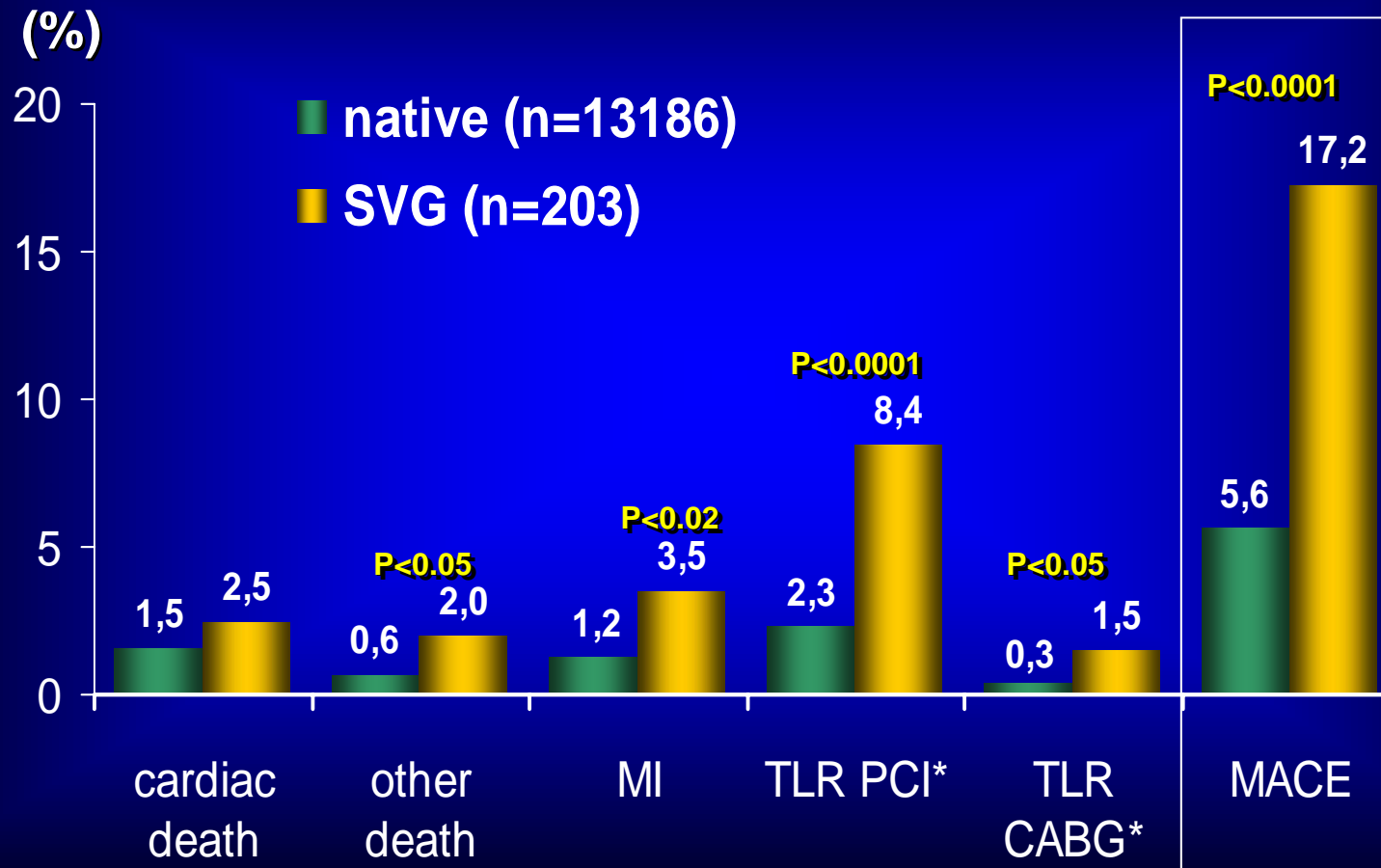
Patients treated at index with SVG and native lesion are not included

SVG

# 360 days follow-up: MACE



## CEC-adjudicated events



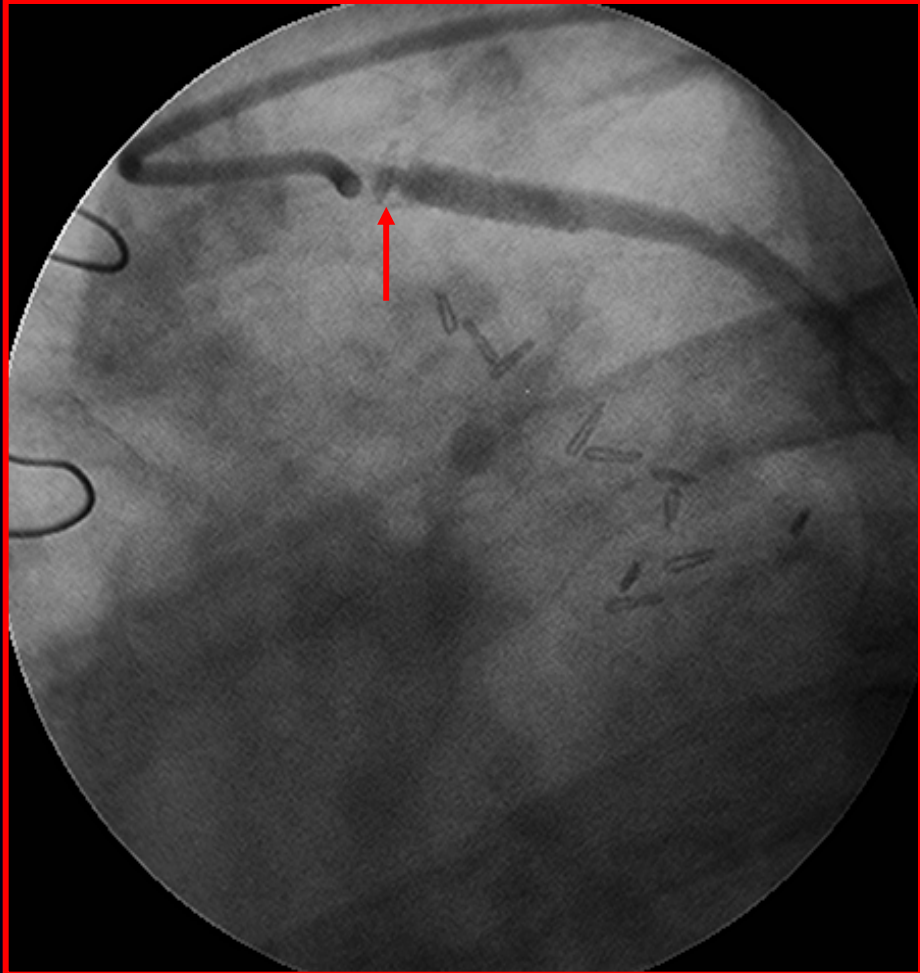
\*Cypher stent related

Patients treated at index with SVG and native lesion are not included

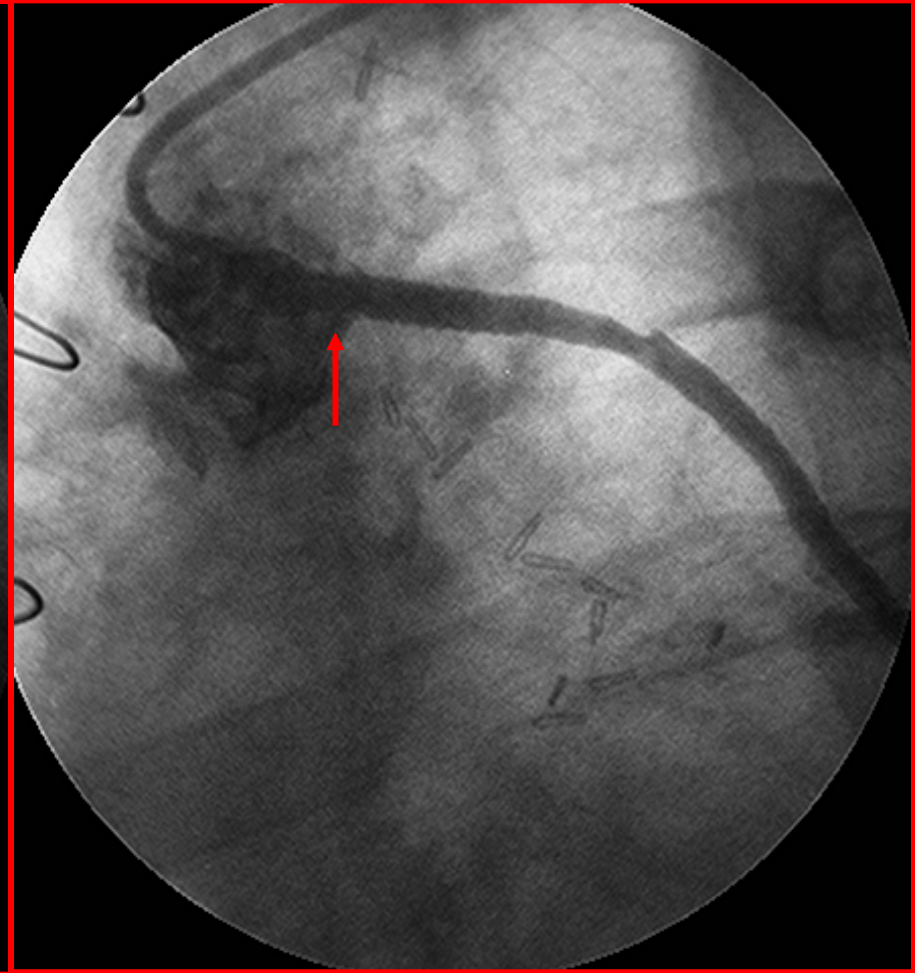


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# Ostial Saphenous Vein Graft In-Stent Restenosis



Pre-Intervention

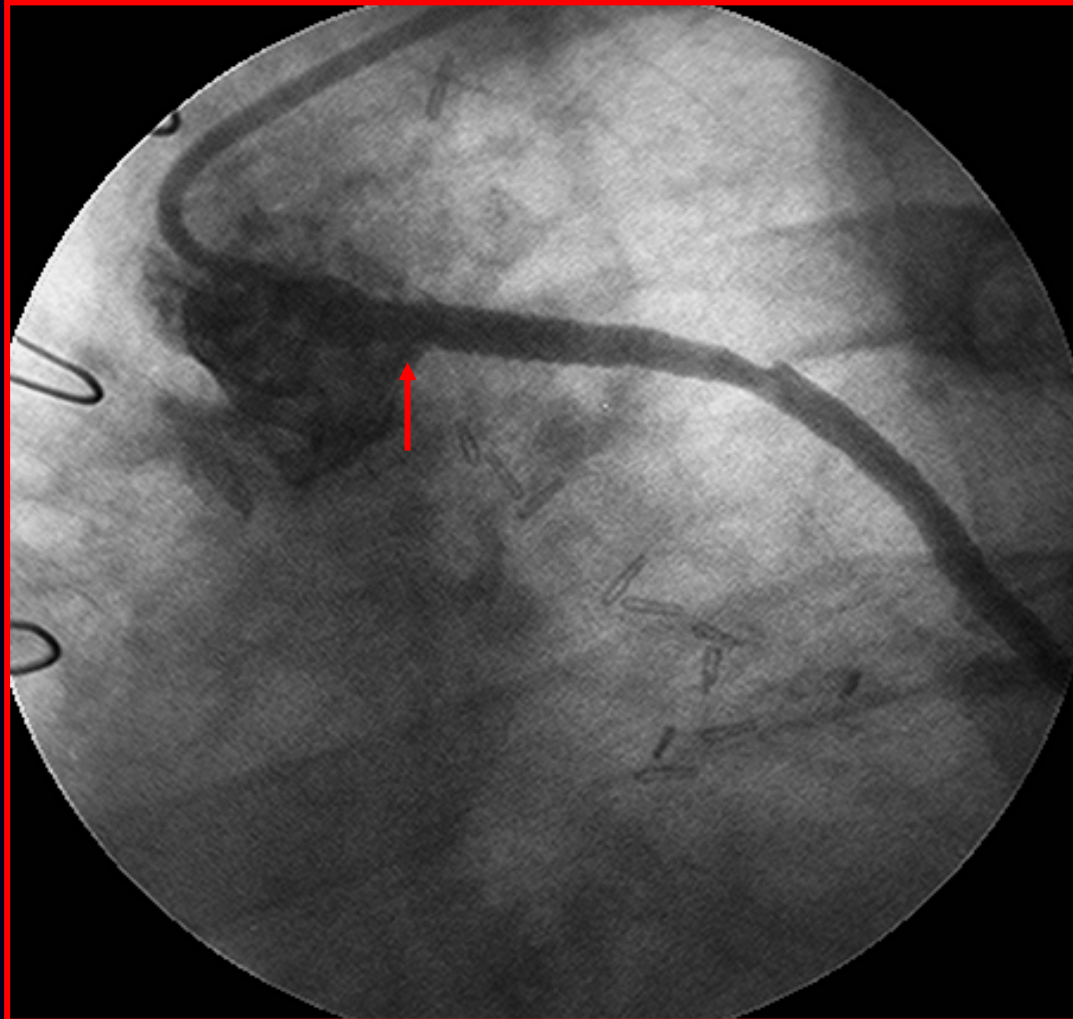


Post 1 Sirolimus-Eluting Stent



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# Sirolimus-Eluting Stent for the Treatment of Ostial SVG - ISR

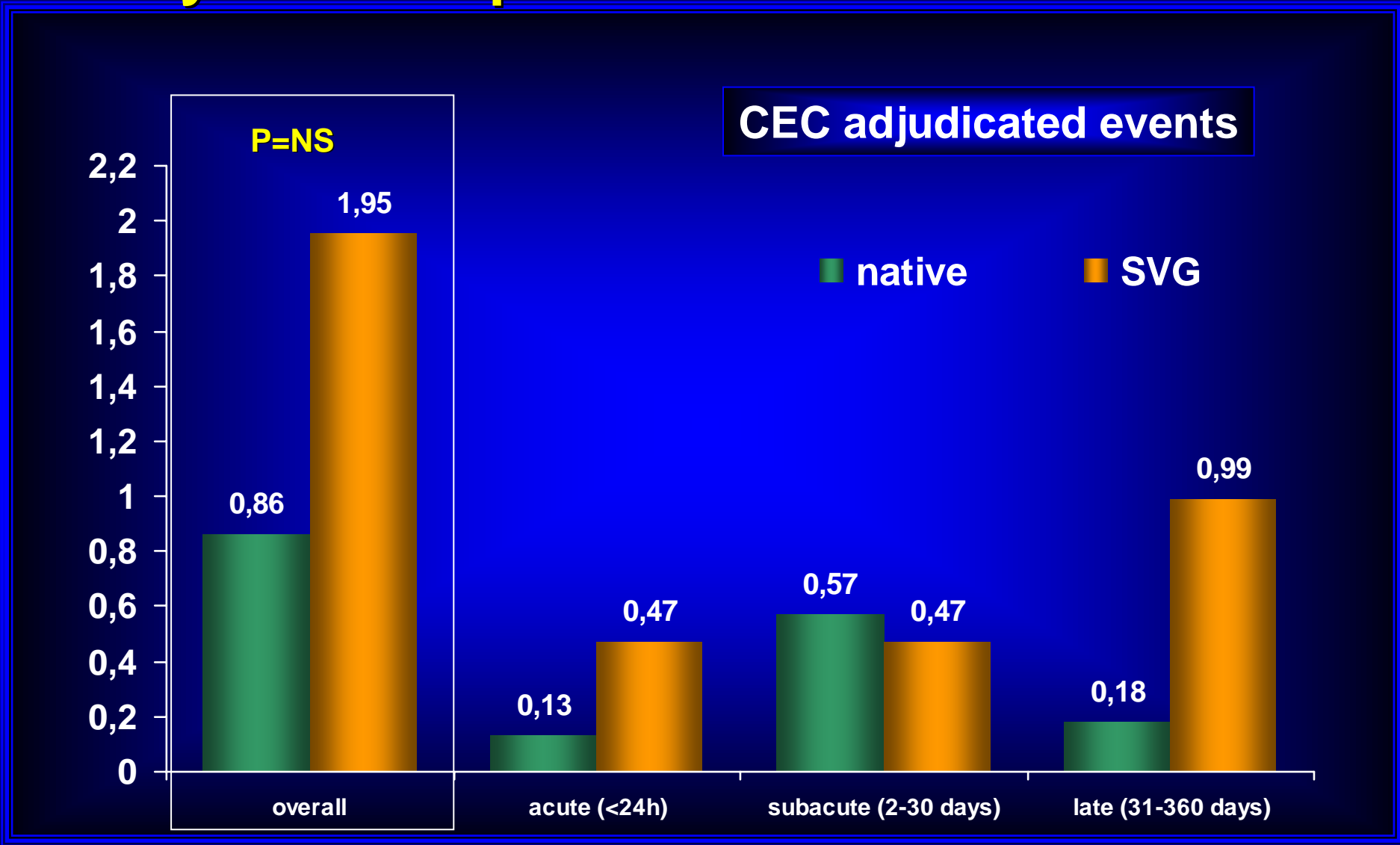


**6-Month Follow-up**



SVG

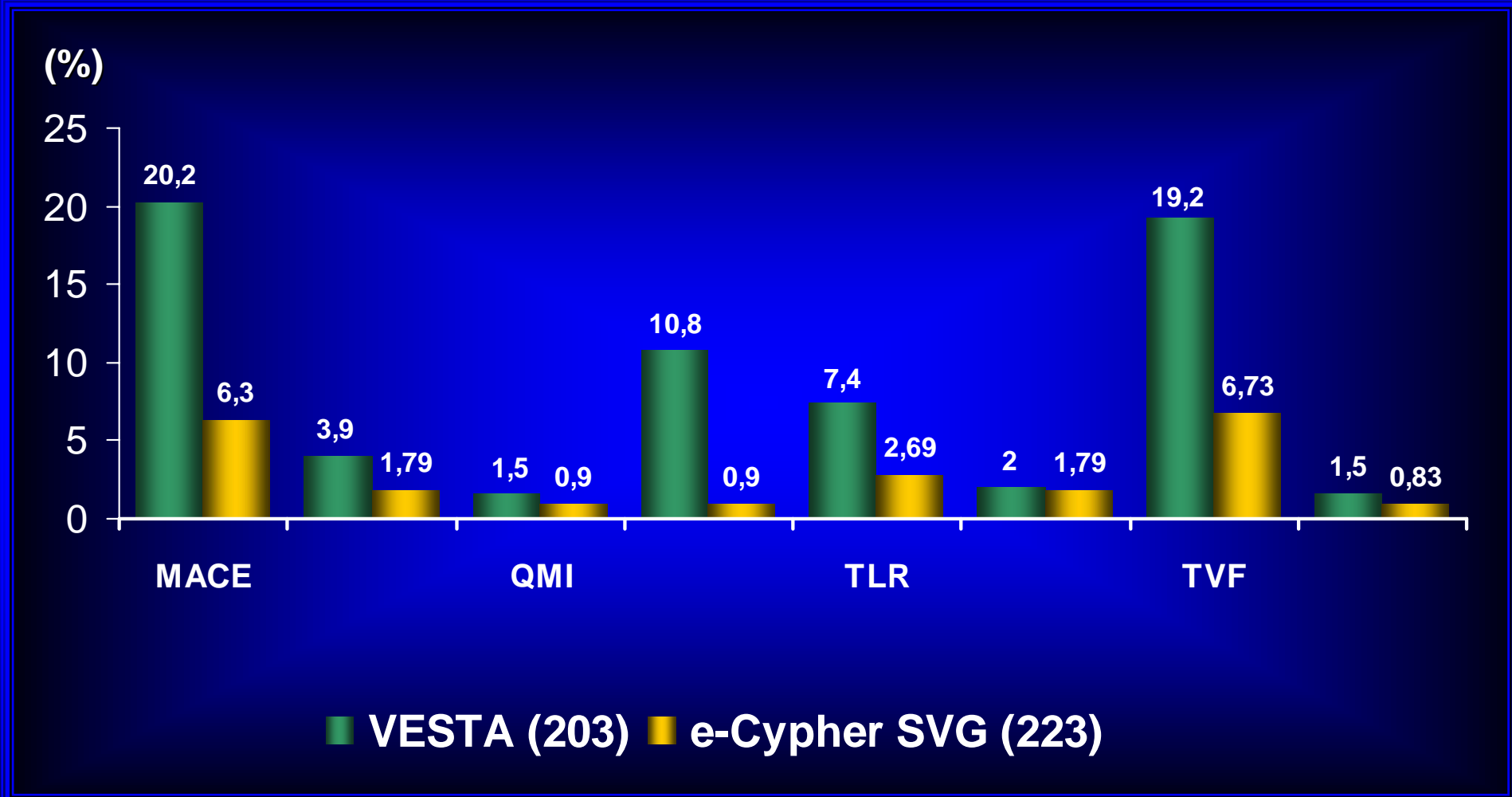
# 360 days follow up: Stent Thrombosis



Patients treated at index with SVG and native lesion are not included

# 6-Month outcome

## e-Cypher SVG cohort (87% FU) vs. VESTA study



**VESTA (The Saphenous Vein graft Intervention using the BX VELOCITY Stent Study)**

# Conclusions



- In the e-CYPHER registry, SES treatment of SVG lesions was associated with a low rate of 1 year TLR (8.5%)
- The higher MACE rates (14.9%) compared to the native group is explained by the higher TVR (non-TLR) rates.
- This still represents a striking improvement when compared with historical bare metal stent data.

# Treatment of Saphenous Vein Graft Lesions With Drug-Eluting Stents

Immediate and Midterm Outcome

Lei Ge, MD,\*† Ioannis Iakovou, MD,\* Giuseppe M. Sangiorgi, MD,\* Alaide Chieffo, MD,\*  
Gloria Melzi, MD,\* John Cosgrave, MD,\* Matteo Montorfano, MD,\* Iassen Michev, MD,\*  
Flavio Airoldi, MD,\* Mauro Carlino, MD,\* Nicola Corvaja, MD,\* Antonio Colombo, MD, FACC\*

**J Am Coll Cardiol 2005;45:989-94**

# Treatment of SVG Lesions with DES

**Milan (N = 61)**  
(3/2002 – 3/2004)

**São Paulo (n = 89)**  
(4/2002 – 10/2005)

**CYPHER**

**35 Pts**

**57.4%**

**TAXUS**

**26 Pts**

**42.4%**

**CYPHER**

**73 Pts**

**81%**

**TAXUS**

**16 Pts**

**19%**

# Baseline Clinical Characteristics

	<u>Milan</u> <u>N = 69</u>	<u>São Paulo</u> <u>N = 89</u>	<u>p</u>
Age, yrs	67 ± 8	68 ± 9	0.4
Male, n (%)	51 (73)	71 (79)	0.34
● Hypercholesterolemie, n (%)	40 (61)	65 (73)	0.04
● Hypertension, n (%)	37 (62)	71 (79)	0.01
● Diabetes Mellitus, n (%)	12 (15)	27 (30)	0.06
Age of SVG, yrs	9 ± 6	10 ± 4	0.2
Unstable Angina, n (%)	18 (26)	26 (29)	0.7
● Multivessel Coronary Disease, n (%)	59 (86)	88 (99)	0.01

# Quantitative Angiography Analysis

	<u>Milan</u> N = 61	<u>São Paulo</u> N = 89	<u>p</u>
- RVD, mm	3.0 ± 0.6	3.0 ± 0.4	ns
- MLD, mm	1.0 ± 0.4	1.0 ± 0.4	ns
- Mean Lesion Length, mm	14.8 ± 12.7	13.2 ± 3.6	0.3

## Baseline Lesion Characteristics

	<u>Milan</u> N = 69	<u>São Paulo</u> N = 95	<u>p</u>
Location of Lesion, n (%)			
- Ostial	13 (19)	20 (17)	0.95
- Proximal	22 (32)	24 (21)	0.35
- Mid	18 (26)	32 (28)	0.30
- Distal	16 (23)	37 (32)	0.04
- Thrombus	9 (13)	13 (12)	0.9

# Procedural Characteristics

	<u>Milan</u> N = 61	<u>São Paulo</u> N = 95	<u>p</u>
● Number of Stents per Lesion, n	1.2 ± 0.6	1.0 ± 0.09	0.02
● Mean Length of Stent per Lesion, mm	29.4 ± 19	19 ± 4.3	0.001
● Max. Balloon Diameter, mm	3.3 ± 0.3	3 ± 0.3	0.01
● Max. Balloon Inflation Pressure, atm	18 ± 4	15 ± 2	0.01
No Reflow , n (%)	0	1 (1.1)	0.4
● Distal Protection Device, n (%)	19 (31)	1 (1.1)	0.001
Glycoprotein IIb / IIIa Inhibitors, n (%)	9 (15)	6 (6)	0.18



# In-Hospital Results

	<u>Milan N = 61</u>	<u>São Paulo N = 89</u>	<u>p</u>
<b>Procedural Success, n (%)</b>	<b>56 (92)</b>	<b>83 (93)</b>	<b>0.7</b>
<b>In-Hospital MACE, n (%)</b>	<b>4 (7)</b>	<b>7 (8)</b>	<b>0.76</b>
- Cardiac Death	0	1 (1.1)	0.4
- Non Cardiac Death	0	0	1
- Q-Wave MI	0	1 (1.1)	0.4
- Non Q-Wave MI	4 (7)	5 (6)	0.8
- TLR	0	0	1
- TVR	0	0	1
- Stent Thrombosis, n (%)	0	0	1

# Six-Month Follow-up

	<u>Milan N = 61</u>	<u>São Paulo N = 85</u>	<u>p</u>
<b>Cumulative Six-Month MACE, n (%)</b>	<b>7 (11)</b>	<b>8 (9)</b>	<b>0.7</b>
- Cardiac Death	0	1(1.1)	0.4
- Non Cardiac Death	1 (1.6)	0	0.23
- Q-Wave MI	0	1 (1.1)	0.4
● - Non Q-Wave MI	5 (8)	5(6)	0.31
● - TLR	2 (3)	0	0.09
- TVR	3 (5)	1(1.1)	0.17
- Stent Thrombosis, n (%)	0	0	1

# Serial Quantitative Angiography Analysis

	<u>Milan</u> <u>N = 50 lesions</u>	<u>São Paulo</u> <u>-</u>
<b>Six-month follow-up, N (%)</b>		
- MLD, mm	2.56 ± 0.95	-
- Late lumen loss, mm	0.37 ± 0.97	-
<b>In-segment restenosis rate, N (%)</b>	5 (10.0)	-
<b>Occlusion of follow-up, N (%)</b>	3 (6.0)	-

# Conclusion

**DES implantation in SVG lesions  
appears safe with favorable mid-  
term outcomes.**

**Even in unfavorable subgroups**

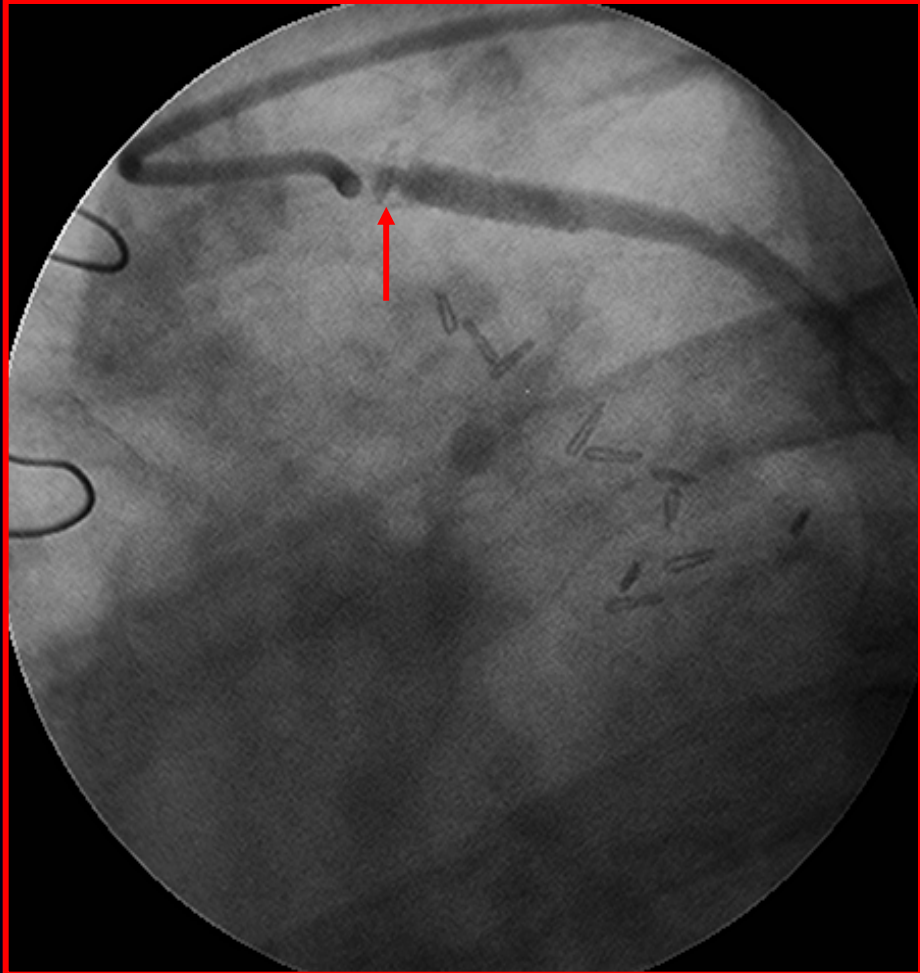
**DES REIGN SUPREME**



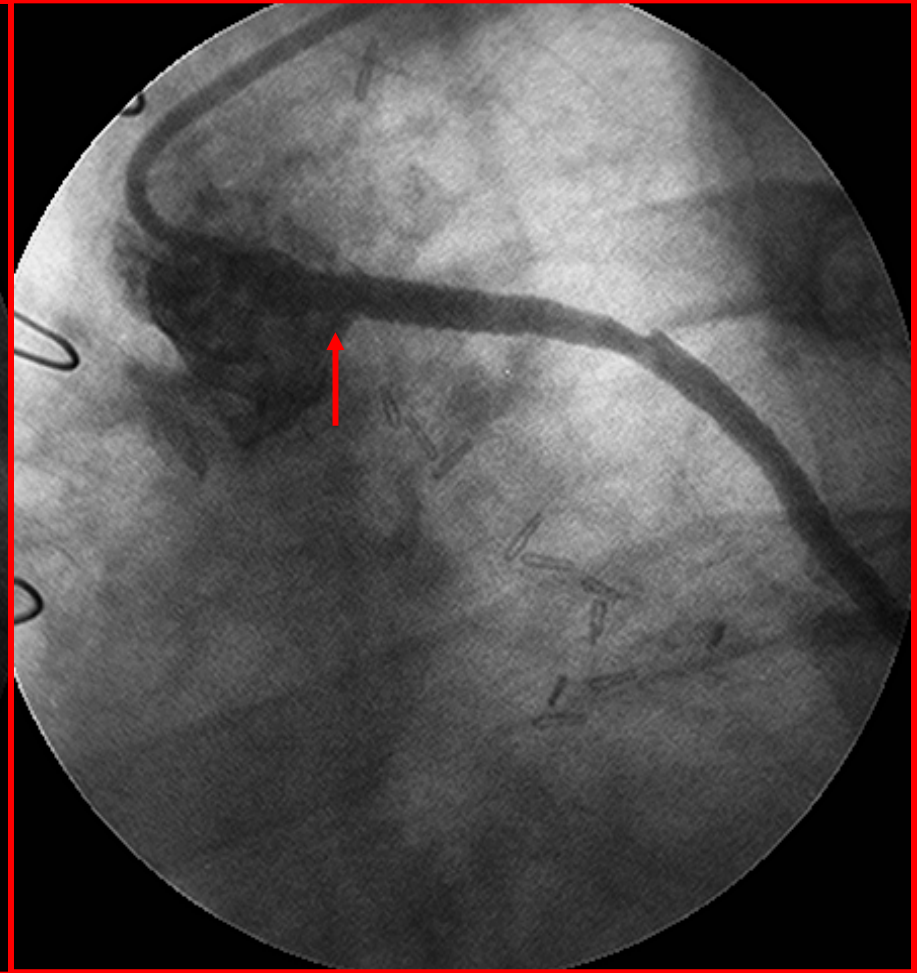


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# Ostial Saphenous Vein Graft In-Stent Restenosis



Pre-Intervention

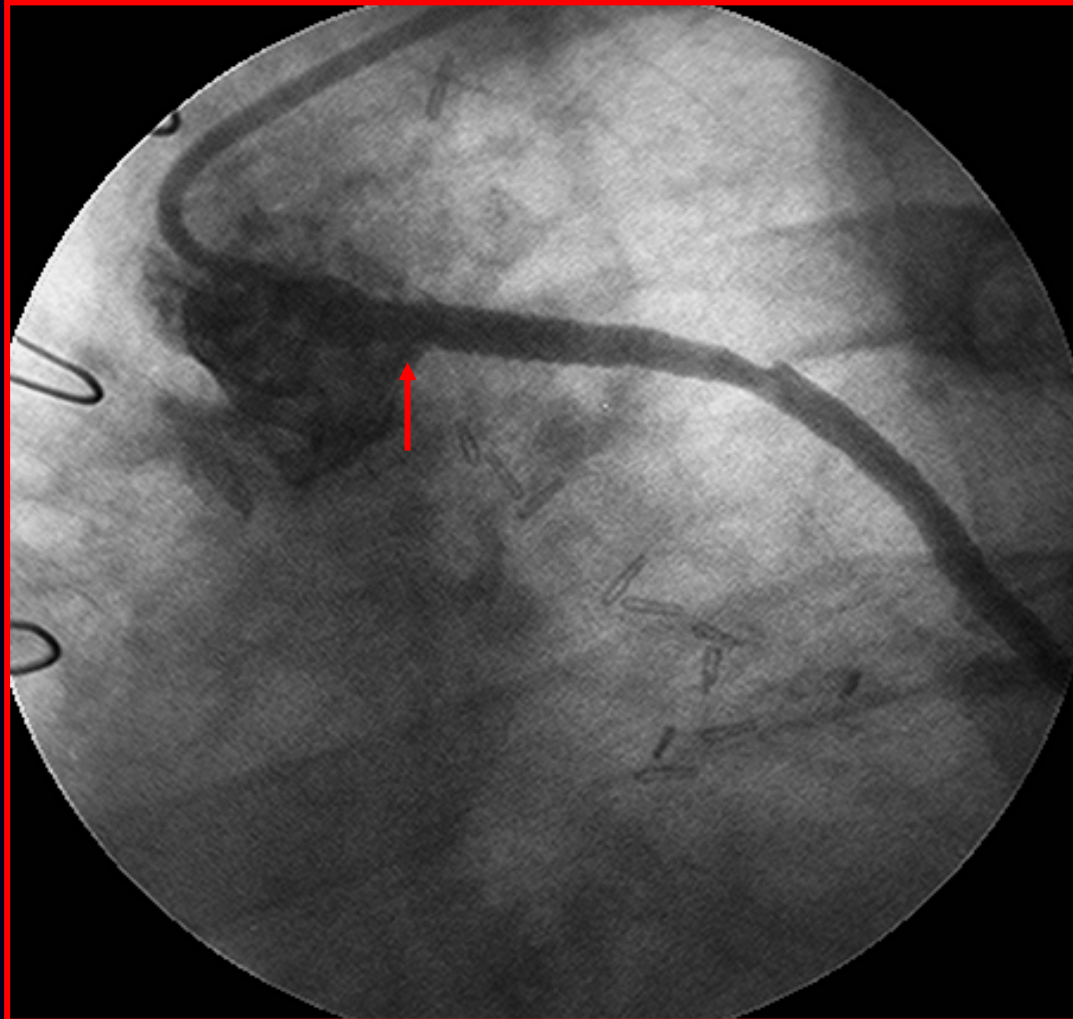


Post 1 Sirolimus-Eluting Stent



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# Sirolimus-Eluting Stent for the Treatment of Ostial SVG - ISR



**6-Month Follow-up**



# Results of Balloon Angioplasty of SVG Lesions

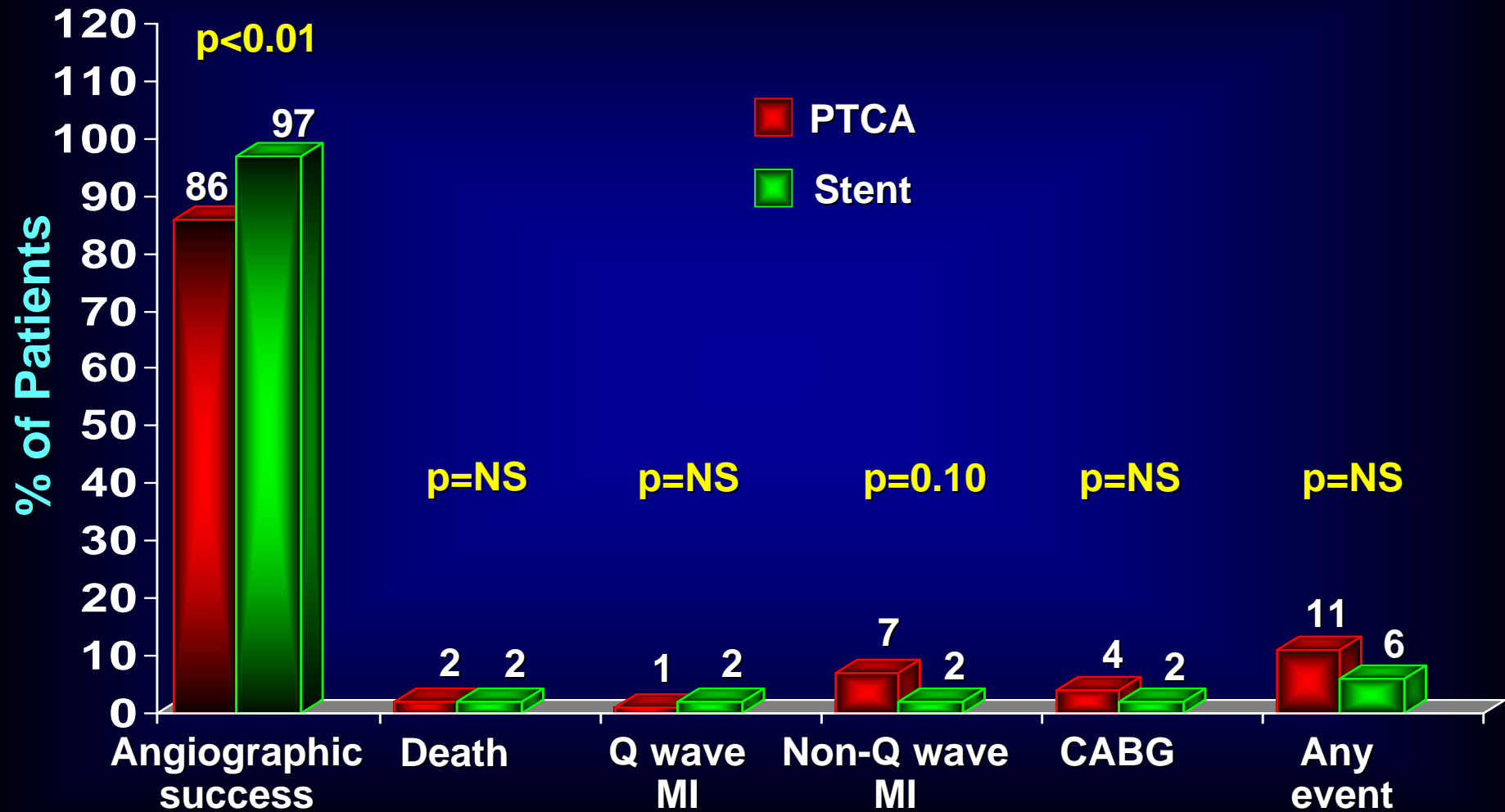
<u>Author</u>	<u>Year</u>	<u>Successful PTCA (%)</u>		<u>MACE (%)</u>
Gruentzig	1979	3/5	(60)	0
Ford	1980	5/7	(86)	0
Douglas	1983	58/62	(94)	1.6
Douglas	1986	216/235	(92)	8
Cote	1987	86/101	(85)	3.9
Pinkerton	1988	93/100	(93)	1
Platko	1989	92/101	(92)	1
Plokker	1991	409/454	(90)	4.7
Douglas	1991	539/599	(90)	18
Miranda	1992	410/440	(93)	4.6

# Results of Stenting of SVG Lesions (BMS)

<u>Stent and Author</u>	<u>Year</u>	<u>Successful PTCA (%)</u>	<u>Early Thrombosis (%)</u>	<u>Restenosis</u>
<b>Palmaz-Schatz</b>				
Fenton	1994	196/198 (99)	0.5	34
Wong	1995	571/589 (97)	1.4	30
Savage	1997	105/108 (97)	1	36
<b>Wallstent</b>				
Strauss	1992	145/145 (100)	8	34
De Jaegere	1996	92/93 (99)	4	-
<b>Various Stents</b>				
Baldus	2000	108/109 (99)	0.9	26
Nishida	2000	97/101 (96)	-	21
Bhargava	2000	711/719 (99)	0.7	19

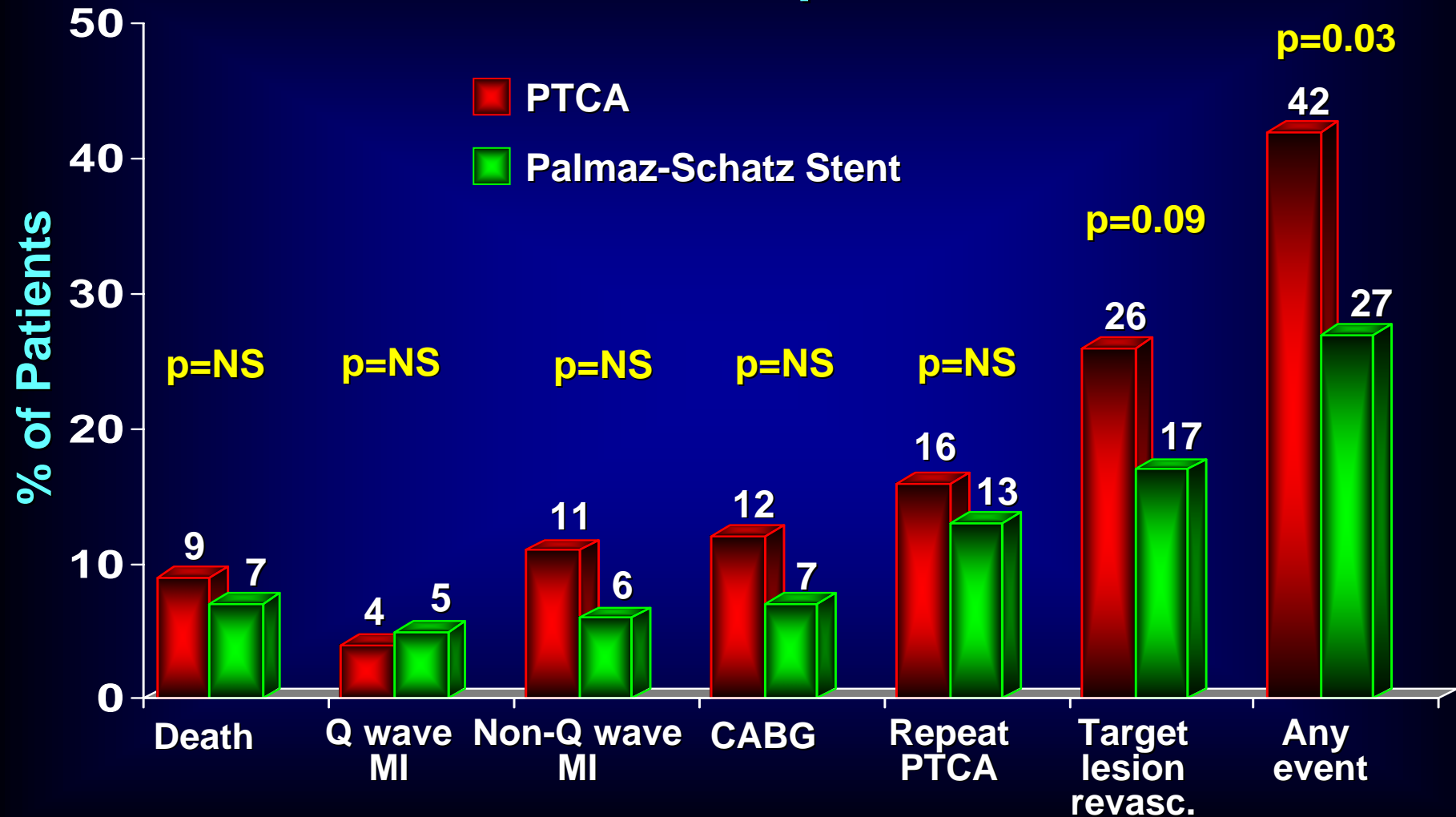
# Results from the SAVED Trial: Palmaz-Schatz Stent x Balloon PTCA

## In-Hospital Events



# Results from the SAVED Trial: Palmaz-Schatz Stent x Balloon PTCA

## Cardiac Events up to 8 Months



# Scope of the Problem

Although the efficacy of CABG has been enhanced, the temporary nature of the palliative effect remains a significant health care problem:

	<u>Incidence %</u>
■ Severe myocardial ischemic syndromes pos-operation	3 – 5
■ Recurrent ischemic symptoms (annually)	4 – 8
■ Progression of disease in native coronary arteries (annually)	5
■ Saphenous vein graft attrition at 10 years	60
■ In-hospital mortality (reoperation)	7
- 70 years and older	10

**These factors favored use of PCI whenever possible**

# Saphenous Vein Graft Lesions

Restenosis remains a major limiting factor in PCIs. How effectively antiproliferative strategies such as the use of DES remains to be determined, but initial reports are encouraging.

# PCI-Procedure



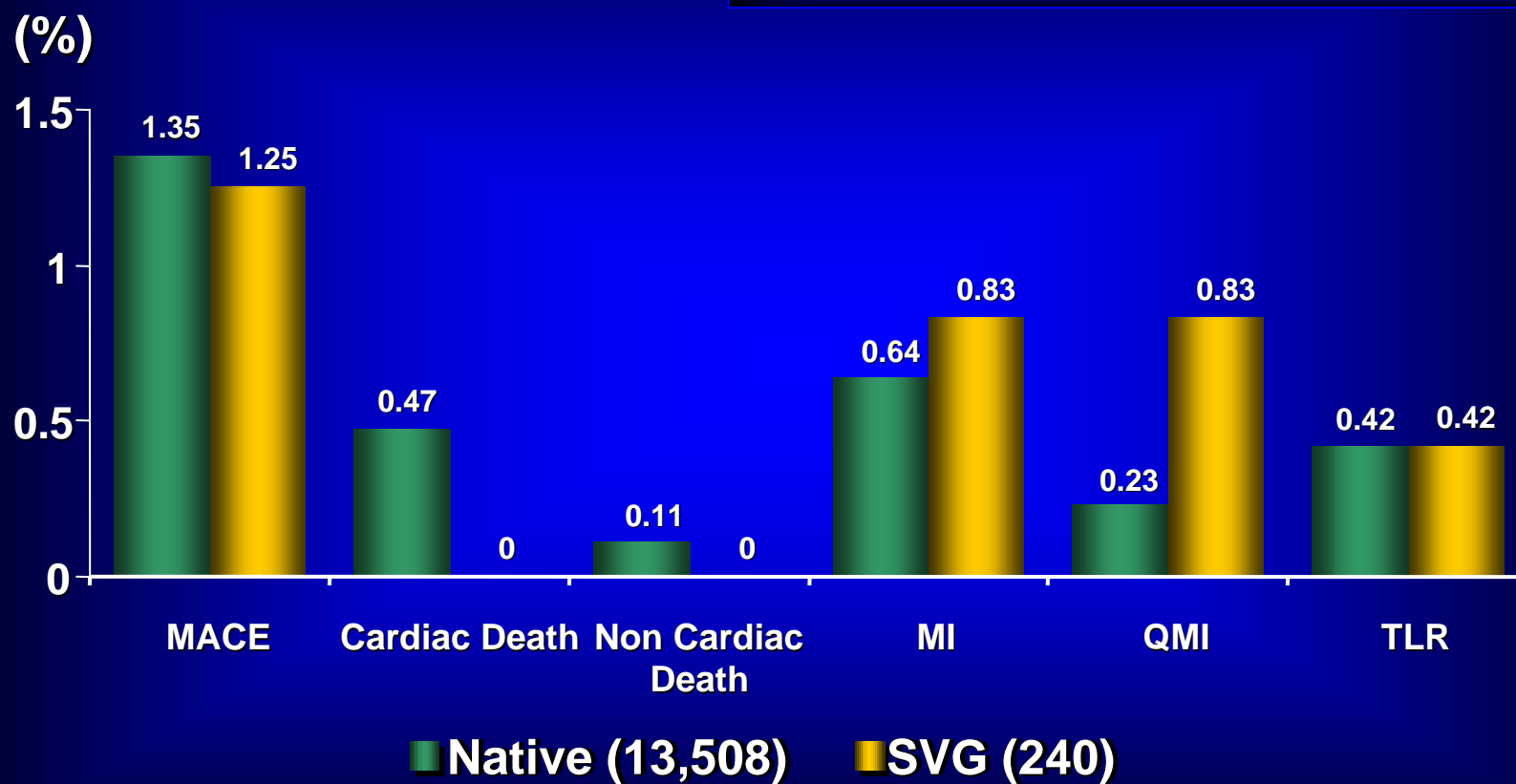
	<b>SVG</b>	<b>Native</b>
<b>Number of patients</b>	<b>262</b>	<b>14,910</b>
<b>SES / patient</b>	<b>1.37 ± 0.69</b>	<b>1.35 ± 0.69</b>
<b>SES / lesion</b>	<b>1.16 ± 0.44</b>	<b>1.15 ± 0.40</b>
<b>Multiple SES (%)</b>	<b>27.9</b>	<b>26.3</b>
<b>Direct Stenting (%)</b>	<b>44.8</b>	<b>33.8*</b>
<b>Post dilation (%)</b>	<b>18.9</b>	<b>21.3</b>
<b>Max deployment pressure (atm)</b>	<b>15.4 ± 4.15</b>	<b>14.6 ± 3.71</b>
<b>Overlapping stents (%)</b>	<b>9.1</b>	<b>9.4</b>
<b>Thienopyridine pre procedure (%)</b>	<b>63.0</b>	<b>67.0</b>

**\*p=0.0001**

# 30-day follow-up: MACE (SVG vs. Native)



Independent adjudicated events





# 6-month follow up: MACE (SVG vs. Native)



Independent adjudicated events

